DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 3, 2015

Halyard Health
Ms. Monica King
Associate Director, Regulatory Affairs
5405 Windward Parkway
Alpharetta, GA 30004

Re: K143053
Trade/Device Name: KIMGUARD® ONE-STEP® Sterilization Wrap
(KC100, KC200)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: March 3, 2015
Received: March 4, 2015

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143053

Device Name
KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200)

Indications for Use *(Describe)*
KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200) are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

• Pre-vacuum steam at 270°F / 132°C for 4 minutes. The wrap was validated for dry times of 20 minutes for models KC100 and KC200.

• 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131°F / 55°C and 40-80% relative humidity for 60 minutes. The wrap was validated for aeration times for EO sterilization of 8 hours at 55°C or 12 hours at 43.3°C for models KC100 and KC200.

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD* ONE-STEP* Sterilization Wraps (KC100, KC200) allowed sterilization of the enclosed devices by the ethylene oxide sterilization and by pre-vacuum cycles.

These models of the KIMGUARD* ONE-STEP* Sterilization Wrap have been validated for use with the ethylene oxide and pre-vacuum cycles in Table 1 (see page 2 of 2)

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Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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TABLE 1: KIMGUARD ONE-STEP* Sterilization Wrap Recommendations for Use with the Pre-Vacuum Steam or Ethylene Oxide[1]*

KIMGUARD* Sterilization Wrap Models	**Intended Loads**	**Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]**	**Descriptions of Loads Used in Sterility Maintenance Validation Study[2]**
KC100	Very Light Weight Package (for example: batteries)	3 lbs.	16 huck towels (17"x 29")
KC200	Light Weight Package (for example: telescope with light cord)	6 lbs.	2 huck towels (17"x 29") 2 fluid resistant U-drapes (68"x 109") 1 fluid resistant universal bar drape (70" x 108")

[1]Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.
[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the KIMGUARD* Sterilization Wraps (i.e.: the number and size of the fluid resistant linens or the weight of the metal mass).

510K SUMMARY

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Applicant's Name, Address, Telephone, FAX, Contact Person

Halyard Health
5405 Windward Parkway, Alpharetta, GA 30004, USA
Establishment Registration Number: 1033422

Contact Name: Monica King, Associate Director of Regulatory Affairs
E-mail: Monica.king@hyh.com
(678) 477-4165 (Telephone)
(678) 254-0347 (Fax)

DATE PREPARED:	April 2, 2015
TRADE NAME:	KIMGUARD* ONE-STEP* Sterilization Wrap (Models KC100 & KC200
CLASSIFICATION NAME:	Sterilization Wrap
COMMON/USUAL NAME:	Sterilization Wrap
PRODUCT CODE:	FRG
DEVICE CLASSIFICATION:	Class II per 21 CFR §880.6850
PREDICATE DEVICES:	KIMGUARD* ONE-STEP* Sterilization Wrap, [510(k) Notification K082554 for ethylene oxide and K082177 for pre-vacuum steam, clearances on May 1, 2009 and March 27, 2009, respectively]

INDICATIONS FOR USE

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200) are intended to be used to enclose another medical device that is to be sterilized by a healthcare provider using:

- Pre-vacuum steam at 270˚F / 132˚C for 4 minutes. The wrap was validated for dry times of 20 minutes.
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/L at 131˚F / 55˚C and 40-80% relative humidity for 60 minutes. The wrap was validated for aeration times for EO sterilization of 8 hours at 55˚C or 12 hours at 43.3˚C.

KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200) are intended to allow sterilization of the enclosed medical device(s) and also maintain sterility of the enclosed device(s) until used.

Test results validated that KIMGUARD* ONE-STEP* Sterilization Wraps (KC100, KC200) allowed sterilization of the enclosed devices by the ethylene oxide sterilization and by pre-vacuum cycles.

These models of the KIMGUARD* ONE-STEP* Sterilization Wrap have been validated for use with the ethylene oxide and pre-vacuum cycles in Table 1 below.

TABLE 1: **KIMGUARD* ONE-STEP* Sterilization Wrap Recommendations for Use with the Pre-Vacuum Steam or Ethylene Oxide[1]**

KIMGUARD* Sterilization Wrap Models	Intended Loads	Maximum Wrapped Package Content Weights Used in Sterility Maintenance Validation Study[2]	Descriptions of Loads Used in Sterility Maintenance Validation Study[2]
KC100	Very Light Weight Package (for example: batteries)	3 lbs.	16 huck towels (17"x 29")
KC200	Light Weight Package (for example: telescope with light cord)	6 lbs.	2 huck towels (17"x 29") 2 fluid resistant U-drapes (68"x 109") 1 fluid resistant universal bar drape (70" x 108")

[1]Individual results may differ due to factors such as variations in handling practices, wrapping techniques, and folding methods. Results may also differ due to the use of irregularly shaped contents, which may put added stress on the wrap. Each healthcare facility should determine for itself which wrap model is most appropriate for each intended use.
[2] It is recommended to not exceed the maximum wrapped package content weights indicated for each wrap model. Furthermore, it is recommended to not exceed the number, weight, and size of individual content types that were validated for the KIMGUARD* Sterilization Wraps (i.e.: the number and size of the fluid resistant linens or the weight of the metal mass).

DESCRIPTION OF DEVICE

KIMGUARD* ONE-STEP* Sterilization Wrap is comprised of two sheets of KIMGUARD* Sterilization Wrap ultrasonically seamed on two edges. This allows for convenient wrapping with two sheets simultaneously.

The sheets of sterilization wrap are square or rectangular fabric produced using a three-layer SMS (spunbond-meltblown-spunbond) process. The wrap fabric (white or blue color) is composed of polypropylene with the addition of less than 2% by weight of phthalocyanine blue pigment (blue fabric only), less than 1% by weight titanium dioxide pigment, and less than 0.009% by weight of a potassium phosphate anti-static treatment. The wrap allows a sterilized package to be opened aseptically.

Table 2: Device Comparison Table - Technological Characteristics

Technological Characteristics	Proposed Device: KIMGUARD* ONE-STEP* Sterilization Wrap K143053	Predicate Device: K3 KIMGUARD* ONE-STEP* Sterilization Wrap K082554, K082177
Manufacturer	Halyard Health	Halyard Health (formerly known as Kimberly-Clark Health Care)
Regulation/Product Code	Sterilization Wrap: 880.6850 / FRG	Sterilization Wrap: 880.6850 / FRG
Device Design	Two sheets of medium blue nonwoven Polypropylene fabric. Each sheet of fabric is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbond polypropylene layers (SMS).	Two sheets of medium blue nonwoven Polypropylene fabric. Each sheet of fabric is composed of three thermally- bonded layers consisting of a Meltblown polypropylene layer surrounded by Spunbond polypropylene layers (SMS).
Method for bonding SMS layers	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)	Thermal bonding with round pin, hexagonal, triangle bond pattern ("daisy" pattern)
Materials	Polypropylene with blue and white Pigments	Polypropylene with blue and white Pigments
Over the Counter Use Device	Yes	Yes
Single Use Device	Yes	Yes
Biocompatibility	Applicable parts of ISO 10993 - Biological evaluation of medical devices (see Table 3)	Applicable parts of ISO 10993 - Biological evaluation of medical devices (see Table 3)
Maintenance of Package Sterility	Real-time testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 365 days.	Real-time testing following sterilization using pre-vacuum steam or Ethylene Oxide supports maintenance of package sterility for 30 days.

SUMMARY OF NONCLINICAL TESTS

Performance testing was conducted to show that the KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200) maintains sterility until used, after completion of the sterilization process in the pre-vacuum and ethylene oxide sterilization systems.

Table 3: Sterilization Wrap Performance Tests

Study	Results
Maintenance of 365-Day Package Integrity	Passed
Ethylene Oxide Sterilant Penetration	Passed
Pre-Vacuum Steam Sterilant Penetration	Passed
Post Sterilization Biocompatibility Testing (Cytotoxicity, ISO 10993-5: 2009; Irritation, ISO 10993-10:2010; Sensitization, ISO 10993-10: 2010.	Passed

OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200) performs as intended as a sterilization packaging system of medical devices when terminally sterilized in the pre-vacuum steam and ethylene oxide sterilization systems. These studies show that the KIMGUARD* ONE-STEP* Sterilization Wrap (KC100, KC200) met the same criteria as the predicate device and are substantially equivalent.